

**Notice of Allowability**

Application No.

09/916,937

Applicant(s)

LUBOCK ET AL.

Examiner

Art Unit

Charles A. Marmor, II

3736

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment and RCE filed 07 April 2004 and the telephonic interview of 11 May 2004.
2. ☒ The allowed claim(s) is/are 1,3-19,31,32 and 40-43 (renumbered claims 1-24).
3. ☒ The drawings filed on 07 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

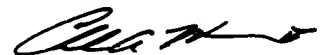
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 05112004.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_



Charles A. Marmor, II  
Primary Examiner  
Art Unit: 3736

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2004 has been entered.

The Examiner acknowledges the amendments to claims 1, 20, 27, 30, 31 and 40 as well as the cancellation of claims 2, 24-26, 28, 33-39 and 44. Claims 1, 3-23, 27, 29-32 and 40-43 are pending, while claims 5-17, 21-23, 29, 30, 32 and 41-43 have been withdrawn from consideration.

### ***Election/Restrictions***

2. Claim 1 is generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 3-23, 29, 30, 32 and 41-43, directed to the species of Figs 2A-2G and 4A-8C are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional

Art Unit: 3736

application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Edward J. Lynch on May 11, 2004.

4. The application has been amended as follows:

#### IN THE SPECIFICATION:

a. In paragraph [0052], the sentence spanning lines 8-11 has been amended as follows:

The tissue cutting devices shown in Figs. 5 and 6 have features described in co-pending applications Serial Nos. 09/057,303, now U.S. Patent No. 6,331,166; 09/146,185, now U.S. Patent No. 6,540,693; 09/159,467, now U.S. Patent No. 6,261,241; 09/238,965, now U.S. Patent No. 6,659,105; 09/356,187, now U.S. Patent No. 6,312,429; and 09/477,255, now U.S. Patent No. 6,471,700 which are incorporated herein by reference.

Art Unit: 3736

b. In paragraph [0062], line 17, --now U.S. Patent No. 6,620,157-- has been inserted following “2000,”.

IN THE CLAIMS:

a. In claim 1, line 7, “that” has been changed to --than--.

b. In claim 4, line 3, --at least one-- has been inserted before “securing”.

c. Claim 6 has been amended as follows:

6. (Amended) The elongated tissue removing device of claim 5, wherein at least one of said inflatable balloons is attached to said elongate shaft proximal of said [region for securing a tissue mass] at least one tissue securing member.

d. Claim 7 has been amended as follows:

7. (Amended) The elongated tissue removing device of claim 6, wherein at least one of said plurality of inflatable balloons is attached to said elongate shaft distal of said [region for securing a tissue mass] at least one tissue securing member.

e. In claim 18, line 2, --at least one-- has been inserted before “tissue”.

f. Claims 20-23 have been canceled without prejudice.

g. Claims 27, 29 and 30 have been canceled without prejudice.

h. In claim 32, line 2, “device” has been changed to --member--.

Art Unit: 3736

5. The following is an examiner's statement of reasons for allowance:

Regarding claims 1 and 3-19, no prior art of record teach or fairly suggest an elongated tissue removing device, as claimed by Applicant, including an elongate shaft having a tissue penetrating tip; a tissue cutting member on a distal shaft section for separating a tissue mass; at least one tissue securing member on the distal shaft section for securing a separated tissue mass to the shaft; and a tissue expander on the distal shaft section proximal to the securing member.

Regarding claims 31, 32 and 40-43, no prior art of record teach or fairly suggest a biopsy device, as claimed by Applicant, including an elongate shaft having a tissue cutting member *on* a distal shaft section for separating a tissue mass and at least one tissue securing member *on* the distal shaft section for securing a separated tissue mass to the shaft in combination with a tissue expander that is adapted to be disposed on the shaft to facilitate removal of a separated tissue mass.

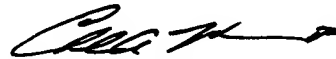
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

cam  
May 11, 2004